No. 31015/45/2014-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013

Subject: Review application of M/s. Vins Bioproducts Ltd. against fixation/revision of ceiling prices of Polyvalent anti-snake venom injection 10 ml vide NPPA notification S.O. No. 2251(E) dated 22/7/2013 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

Ref. 1) Applicant Review application dated 19.8.2013
2) NPPA notification under review S.O. No. 2251(E) dated 22/7/2013
3) Record Note of discussions held in the personal hearing held in the matter on 27.9.2013

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 2251(E) dated 22/7/2013 fixed/revised ceiling price of Polyvalent anti-snake venom injection 10 ml under DPCO, 2013.

2. And whereas aggrieved by the above notification, M/S Vins Bioproducts Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 19.8.2013 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No. 2251(E) dated 22/7/2013 fixing Ceiling price of Polyvalent anti-snake venom injection 10 ml under DPCO, 2013 included in Schedule-I of the order.

3. The grievance of the Petitioner raised in their review application dated 19.8.2013 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the Record Note of discussions held in the hearing on 27.9.2013. Record Note of discussion is made integral part of the review order. After considering the comments of NPPA, the Petitioner has raised the following points, on which comments given by NPPA representative, during the hearing and Government's comments on the issue is recorded subsequently against each point:

Company's submission during personal hearing

4. During the personal hearing the company had mentioned that Polyvalent Anti-snake Venom Injection 10 ml is available in 2 forms – one in liquid form and another in lyophilized powder form. The NPPA notification does not distinguish between these two forms. The liquid form is produced directly from the anti bodies developed by them. However, for producing lyophilized form there is a long drawn process is involved. The production of liquid form is normally double than the lyophilized form. Though both the products are, as per the namology, the same but their pricing cannot be the same and therefore they are two different products and should be treated differently. The company also mentioned that 10 ml. used in the notification is a unit while the actual strength should be "Polyvalent Enzyme Refined, Equine Immunoglobulin's Each 1 ml. of antiserum neutralizes not less than 0.6 mg of dried India cobra (Naja naja) venom 0.45 mg of dried common krait (Bungarus Caeruleus) Venom 0.6 mg of dried russell's viper(Doboja russlelli) venom 0.45 mg of dried saw scaled viper (Echis carinatus) venom" which means that the strength should cover the bites of various types of snakes mentioned in this strength. Without this the patient cannot be protected from all types of snakes. The company also mentioned that since the revised price is not very economical, different companies are reducing their production level and

apprehended that non protection of prices will lead to non-availability of anti snake venom in the market.

NPPA comments:

5. NPPA representative mentioned that NPPA is fixing the prices of NLEM drugs considering the provisions of DPCO 2013. In the NLEM this medicine Polyvalent Anti-snake Venom Injection is mentioned in the 19.2 section where there is no such distinction in the NLEM about the lypholised powder form and in other form etc. The strength of the venom is also not mentioned in the NLEM. The composition of Polyvalent Anti-snake Venom Injection is not indicated in the NLEM list. The route of administration is injection and strength is 10 ml. as indicated in the NLEM.

6. The ceiling prices fixed by the NPPA are in line with the simplification mentioned in the NLEM. Further the data provided IMS health was considered in fixing the ceiling price of this medicine wherein only the conventional products have been indicated. The representation of the company has also been forwarded to IMS for reconfirmation of the data on 17.9.2013. The NPPA is fixing the prices in all the cases as per the specifications notified in the NLEM. Further the NPPA has not received any shortage report of this drug after fixing the above ceiling price.

7. It is mentioned by NPPA that as per NLEM 2011, the Anti-snake venom is specified as injection 10 ml and there is no distinction made about lyophilized form. The price notified by the NPPA is for the drug form listed in the NLEM. This price is applicable to all the manufacturers producing Polyvalent Anti snake Venom in all the 10 ml vial injection form. The data provided by IMS-Health considered is related to only M/s Biological Evans, M/s Bharat Serum and M/s Serum Institute. The NPPA has also taken up the matter with the IMS regarding other companies like M.s Hopkinns and M/s Vins Bioproducts.

8. It is mentioned that the data provided by IMS-Health has been considered after clubbing the MAT value of specific medicines manufactured by the same company in different brand names/generic names for determining the market share (of more than or equal to 1%) for working out the ceiling prices in terms of the definition of the term “brand” as given in Para 2(c) of the DPCO 2013.

9. Shri Tyagi, Dy. Industrial Adviser, Department of Pharmaceuticals mentioned that there is definitely a difference in a normal liquid form of Polyvalent Anti-snake Venom Injection and lyophilized form. The difference lies in terms of physical appearance, shelf life, storage conditions etc.

Points for consideration:

10. It is seen from the discussion and the comments of Dy. Industrial Adviser of the Department that there is a distinction between the liquid form and the lyophilized form which is in the powder form. There is a difference in the storage conditions while liquid form can be stored at 2–8 C, the powder form can be stored at normal room temperature. Shelf life of the product is doubled after it is converted to lyophilized form. Though NLEM does not distinguish between two variants which vary significantly on cost, storing conditions, shelf life and the mobility aspect. Since NPPA is mandated to follow the DPCO 2013, the action of NPPA is in order. However, there is need for technical advice. Hence the issue was referred to Standing Technical Committee for giving their recommendations.

Standing Technical Committee:

11. A Standing Technical Committee was constituted vide OM dated 20.12.2013 to decide the technical issues raised by various companies during the review under para 31 of DPCO, 2013. The Experts in the Committee included members from Department of Science and Technology; CDSCO; NIPER, Mohali; Department of Biotechnology; KAPL.

12. The STC had several meetings to frame its principles. The issue of ASVS was considered by the Committee. The committee was of the considered view that liquid form and lyophilized powder form are different forms of Polyvalent anti-snake venom serum injection. Certain aspects like manufacturing process, presentation, storage conditions and shelf life etc. of the two forms are different. As per section 4.2 of Schedule 1 of the DPCO 2013, the injection polyvalent solution and lyophilized polyvalent serum has been mentioned separately. Therefore, as done in case of capsules and tablets of a medicine of given strength in Schedule I of DPCO 2013, the same can be done here also.

13. The recommendations of the STC were accepted by the Government.

Government's recommendation

14. Polyvalent anti-snake venom serum injection in liquid form and lyophilized powder form may be priced separately in separate baskets under DPCO 2013. NPPA may also revalidate the data as mandated under para 9(1) of DPCO 2013. In this specific case of anti-snake venom, the matter for differential prices for different variants can be addressed by fixing the price under Section 4.2 of the schedule 1 of DPCO,2013 which provides for Injection as well as lyophilyzed polyvalent serum instead of fixing it under Section 19.2 of the schedule.

Based on the above and other documents on record, the Government has decided as under:

> "In this specific case of anti-snake venom, the matter for differential prices for different variants can be addressed by fixing the price under Section 4.2 of the schedule 1 of DPCO,2013 which provides for Injection as well as lyophilyzed polyvalent serum instead of fixing it under Section 19.2 of the schedule."

Issued on this date 20th January, 2015.

(Anil Jain)
Under Secretary to the Govt. of India
For and on behalf of the President of India

To

1. M/s. Vins Bioproducts Ltd.,
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   Hydeabad-500034
2. The Member Secretary,
   National Pharmaceutical Pricing Authority,
   YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. Technical Director, NIC, Shastri Bhawan, New Delhi with the request to upload on the Department's website.